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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,416	10/27/2003	Ragina Naidu	740082.407	5617

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EXAMINER

COVINGTON, RAYMOND K

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,416

Applicant(s)

NAIDU, RAGINA

Examiner

Raymond Covington

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/13/05 3/26/05.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7-17, 37, 38 and 51 is/are allowed.
- 6) ☒ Claim(s) 6, 18-36, 39-50 and 52-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/13/05 3/26/05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 18 contain terms, DBU, DEAD, DCC and DMSO respectively, are not defined. The first use of these terms in the claims should be written out.

Claims 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There are two claim 58 in the claims. Correction or cancellation is required.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 18-36, 39-50 and 52-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ojima US 6,187,916 taken with Zamir et al US 6,576,777,

Magri et al Jol. Nat. Prod. Vol. 51 no. 2 pp 298-302 (1988), Klein et al J. Med. Chem. Vol. 38 pp 1482-1492 (1995) and Holton et al US 5,489,601.

Determination of the scope and content of the prior art (MPEP 2141.01)

Ojima teaches taxane derivatives and processes for preparation of the type recited in the claims. See, for example, column 1 lines 30-45, column 2 lines 30-60, applied to applicants' claims 19-21, 25, 26 and 36 in particular, column 3 lines 1-62, applied to applicants' claim 24 in particular, column 4 lines 54-70, column 7 lines 1-70, columns 9-10. Zamir et al teach analogous compounds and processes. See, for example, column 5 lines 1-50, applied to applicants' claim 18 in particular, column 13 lines 1-54, applied to applicants' claim 19 in particular, columns 15-16 applied to applicants' claims 52-54 in particular. Magri et al is likewise analogous, see page 298 and page 301. Klein et al teaches analogous compounds and processes. See, for example page 1483 right column, claims 19, 29, 32, 33, page 1484 schemes 2-3, page 1485, claim 45. Holton et al is also analogous, see, column 6 lines 25-70, for claim 52, column 7 lines 35-70 and column 8 lines 15-70, for claim 19

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The references differ in the types of protecting groups employed, the position of the attached dioxo ring, the presence of t-butyl or phenyl on the position 13 substituent. However, choice of protecting groups for taxane derivatives is well known to one of ordinary skill in the art as shown by the various protecting groups disclosed in the cited references. The close structural similarity in the positional placement of the dioxo formed ring would have been obvious.

Finding of prima facie obviousness--rational and motivation (MPEP 2142-2413)

In view of the art as a whole the claims invention would have been obvious to one of ordinary skill as the use of somewhat different but otherwise analogous starting materials I otherwise known processes to obtain known products would not have been unexpected and therefore unpatentable.

Claims 1-5, 7-17, 37 38 and 51 drawn to azide N3 containing products and processes are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RKC

Raymond Covington
Examiner
Art Unit 1625


9/19/05